K070483

1 of 2

510(k) SUMMARY

APR 19 2007

Submitter's name: Leone SpA
Address: 50 Via P. a Quaracchi
Sesto Fiorentino, Italy I-50019
Phone +39.055.30441
Fax +39.055.374808

Name of contact person: Elia Ladani
Leone SpA
50 Via P. a Quaracchi
Sesto Fiorentino, Italy I-50019
quality@leone.it
Phone +39.055.30441
Fax +39.055.304444

Date the summary was prepared: February 8, 2007

Name of the device: Leone Monoimplant for O-ring overdenture
Trade or proprietary name: Leone Monoimplant for O-ring overdenture
Common or usual name: Dental implant
Classification name: Endosseous Dental Implant

The legally marketed device to which we are claiming equivalence [21 CFR 807.92(a)(3)]:

Imtec Corporation, IMTEC Sendax MDI and MDI Plus (K031106)
Leone SpA, Leone Implant System (K050586)

Description of the device:

The Leone Monoimplant for O-ring overdenture is a one-piece endosseous dental implant where an endosseous portion and an abutment portion are defined. The implant is composed of titanium alloy for surgical use. The endosseous portion is a self-tapping screw with a sandblasted surface, while the abutment portion is made of a smooth tapered neck favouring soft tissues healing and mucosal seal and a ball shape top for the connection to the overdenture's micro-housing. The monoimplant is supplied in different sizes and is intended for use in the overdenture O-ring therapy in the treatment of the total lower edentulism.

Intended use:

The Leone Monoimplants for O-ring overdenture are indicated as therapy for the stabilization of removable prosthesis on lower arch. The Leone Monoimplants for O-ring overdenture are designed to be

surgically inserted in the bone structure of the mouth, exclusively in the mandible at the level of the area between the two foramina, as an anchorage system for total removable prosthesis. To properly support a removable prosthesis, four monoimplants have to be inserted.

Summary of the technological characteristics of our device compared to the predicate devices:

Device Name	Leone Monoimplant for O-ring overdenture	IMTEC Sendax MDI and MDI Plus	Leone Implant System
Product code	DZE	DZE	DZE
Regulation no.	872.3640	872.3640	872.3640
Applicant	Leone SpA (Italy)	Imtec Corporation (USA)	Leone SpA (Italy)
510(k)	This submission	K031106	K050586
Intended use	The Leone Monoimplants for O-ring overdenture are designed to be surgically inserted in the bone structure of the mouth, exclusively in the mandible at the level of the area between the two foramina, as an anchorage system for total removable prosthesis.	The IMTEC Sendax MDI and MDI PLUS are self-tapping titanium threaded screws indicated for long-term intra-bony applications. Additionally, the MDI may also be used for inter-radicular transitional applications.	The Leone Implant System is designed to be surgically inserted in the bone structure of the mouth in order to replace missing teeth. It can work as an abutment system for partial/total prosthetic restorations or as an anchorage system for removable prosthesis.
Material	Titanium Alloy	Titanium Alloy	Titanium Alloy
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Sterility	Sterile	Sterile	Sterile

Conclusion:
The Leone Monoimplant for O-ring overdenture intended use is equivalent to the IMTEC Sendax MDI and MDI Plus long-term application and to the Leone Implant System anchorage for removable prosthesis in case of the stabilization of an overdenture. The Leone Monoimplant for O-ring overdenture and the predicate devices are composed of the same biocompatible titanium alloy for surgical use, they are substantially equivalent in design, physical characteristics, functional performance, labelling, potential adverse effects. Based on the information provided herein, we conclude that the Leone Monoimplant for O-ring overdenture is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. The Leone Monoimplant for O-ring overdenture raises no new issues of safety or effectiveness. Therefore, safety and effectiveness are reasonably assured, and substantial equivalence is supported, justifying 510(k) clearance of the Leone Monoimplant for O-ring overdenture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Elia Ladani
Quality Manager
Leone SpA
50 Via P. a Quaracchi
Sesto Fiorentino,
ITALY I-50019

APR 19 2007

Re: K070483
Trade/Device Name: Leone Monoimplant for O-ring Overdenture
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: April 10, 2007
Received: April 12, 2007

Dear Mr. Ladani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K070483

Device Name: Leone Monoimplant for O-ring overdenture

Indications For Use:

The Leone Monoimplants for O-ring overdenture are indicated as therapy for the stabilization of removable prosthesis on lower arch. The Leone Monoimplants for O-ring overdenture are designed to be surgically inserted in the bone structure of the mouth, exclusively in the mandible at the level of the area between the two foramina, as an anchorage system for total removable prosthesis. To properly support a removable prosthesis, four monoimplants have to be inserted.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kei Mulay for MSR

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K070483

Page __ of ___